# PSJ3 Exhibit 374

# Summary of the DEA-HDMA Meeting on Suspicious Orders Meeting Date: Sept. 7, 2007

**HDMA Attendees:** Scott Melville, Anita Ducca, David Durkin (OFW)

**DEA Attendees**: Mark Caverly, Kathy Gallagher, Mike Mapes, Lisa Sullivan

### Summary: After introductions, HDMA

- Gave a brief overview of the Association, the Distribution industry, and described some of HDMA's safety policies and initiatives.
- Indicated our interest in having the DEA explain their "Internet Distributor Initiative" and understanding the DEA's expectations.

DEA then provided us with their latest organization chart and explained the responsibilities of each section. Mike Mapes then provided HDMA with the same presentation that DEA has provided to several wholesale distributors regarding suspicious orders. (Attached) He noted that DEA had met with approximately 15-20 wholesale distributors one-on-one. They had prioritized who to meet with on a combination of wholesale distributor sales volume and tracing back to where they felt the source of products for illicit Internet pharmacies were located.

# Key "take aways" from the meeting were:

- DEA's policy was to expect more than just reporting "suspicious orders". If there was a suspicious order, the distributor should either stop the delivery or should evaluate the customer further before delivering it.
- Simply complying with the "suspicious orders" regulatory requirement does *not* mean, in the agency's view, that the registrant is maintaining an effective program to detect and prevent diversion.
- DEA indicated that they did not have the resources to inspect every pharmacy; therefore it was important for the distributor to "know their customers."
- The DEA criteria reflected in their September 2006 letter to registrants was "for background" and they do not expect the wholesale distributor to violate privacy or other laws to find out what they needed to know about their customers.

### Additional points DEA made included:

- DEA was clear that the "system" mentioned above did not need to be the same for each wholesale distributor.
- DEA provided examples of what a wholesale distributor should do to "know their customers" and what to look for. For example, they mentioned inspecting pharmacies. They also mentioned such actions as "doing Google searches" to determine if the pharmacy's name was affiliated with an internet site, and getting information from the state as to the nature and number of prior legal actions against a pharmacy. And they gave a checklist of "Internet Pharmacy Decision Questions" meant as a guide. (See attachment

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- page 2 after the organization chart) However, they did not give specifics as to how to go about completing the checklist beyond the examples above, and it was unclear if they expected wholesale distributors to inspect all pharmacies
- DEA also does not want to receive suspicious order reports that merely reflect volumes that went over a threshold, they wanted reports that are "true" suspicious orders. Similarly, they do not want to receive what they called "excessive purchase" reports which had been used in the past.
- DEA also indicated that they were not going to make a decision for the wholesale distributor as to when an order was "suspicious". They feel this is up to the distributor.
- DEA suggested that distributors should check on the pharmacy's prescribing physicians. They pointed to some states having on-line systems by which a distributor could check to see if a prescribing physician had a valid DEA registration. DEA suggested that distributors ask who the doctors are that are prescribing, where the pharmacy is geographically with respect to its prescribing doctors and the patient population.

### **Conclusion:**

At the close of the meeting, HDMA indicated that we would be meeting with our members and discussing this further. We indicated that we might be suggesting future meetings between our two organizations and our members.

## **HDMA** questions and assessment:

- DEA attempted to place the Sept. 2006 letter into a better light than what it appeared to be on its face.
- DEA's expectations are clearly heightened. HDMA would like to ask its members about the impact of these expectations. For example,
  - o Are all members capable of inspecting their pharmacy customers?
  - O How difficult is it to put a "system" in place that not only monitors suspicious orders but also stops the order and/or evaluates the customer against the order?
  - O How often does a suspicious order fall into a "gray area" for example, the order is larger than a pre-established threshold, but not so far over that it is clearly out of line with that pharmacy's customer base and size?
- Do we need better clarification and/or a written statement from the DEA about when to send a suspicious order and when not to send it even if it is over a threshold?
- Do we have recommendations for DEA as to how to approach this problem in a way that simplifies things for the wholesale distributor? Would some of our anti-counterfeit policies fit this situation? E.g., ask them to support RFID? Recommend, (and press for) better pharmacy inspections by DEA prior to licensure?